

United States Court of Appeals  
For the Eighth Circuit

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No. 13-2084

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Key Medical Supply, Inc., a Minnesota corporation

*Plaintiff - Appellant*

v.

Sylvia Matthews Burwell,<sup>1</sup> Secretary of the United States Department of Health and Human Services, in her official capacity; Marilyn Tavenner,<sup>2</sup> Acting Administrator of the Centers for Medicare and Medicaid Services, in her official capacity

*Defendants - Appellees*

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Midwest Association of Medical Equipment Suppliers, Inc.

*Amicus on Behalf of Appellant(s)*

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Appeal from United States District Court  
for the District of Minnesota - Minneapolis

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<sup>1</sup>Secretary of Health and Human Services Sylvia Mathews Burwell is substituted for her predecessor, Kathleen Sebelius. See Fed. R. App. P. 43(c)(2).

<sup>2</sup>Marilyn Tavenner was confirmed as Administrator of the Centers for Medicare and Medicaid Services on May 15, 2013.

Submitted: May 14, 2014  
Filed: August 25, 2014

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Before WOLLMAN, MELLOY, and BENTON, Circuit Judges.

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MELLOY, Circuit Judge.

Key Medical Supply, Inc. ("Key Medical"), a medical equipment provider in the Minneapolis-St. Paul area, alleges that the Department of Health and Human Services' Centers for Medicare and Medicaid Services ("CMS" or "the Agency") exceeded its statutory authority when implementing a competitive-bidding system for Medicare's pricing of medical equipment and supplies. Key Medical acknowledges that the governing statute contains a strongly worded ban on administrative and judicial review. Key Medical argues, however, that review should be available because the Agency acted in an *ultra vires* manner by: (1) imposing arbitrary and non-competitively-derived maximum bid caps for certain products; (2) grouping inexpensive commodity products with more expensive custom-fit products for bidding purposes; and (3) applying the competitive bidding program in a manner that interferes with the separate state/federal Medicaid system. Key Medical also argues that review should be available for constitutional claims asserting that the Agency's actions deprived Key Medical of due process and effected an unconstitutional taking of Key Medical's "business." The district court<sup>3</sup> rejected Key Medical's arguments and determined that the statutory bar on review precluded jurisdiction. We affirm.

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<sup>3</sup>The Honorable Donovan W. Frank, United States District Judge for the District of Minnesota.

## I. Background

### A. General Background: 42 U.S.C. § 1395w-3 Medicare Competitive Bidding System for Certain Items and Services

In 2003, Congress amended Medicare to control costs for durable medical equipment, prosthetics, orthotics, and supplies, based in part on a conclusion that Medicare and beneficiaries were overpaying substantially for such items. H.R. Rep. No. 108-178, pt. II, at 144 (2003) ("The Office of Inspector General has documented that taxpayers and Medicare beneficiaries are paying millions more for durable medical equipment than other programs, such as the Federal Employees Health Benefit Program (FEHBP)."). The amendments required the Agency to phase in a competitive bidding system to replace an existing government-defined price schedule. Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, title III, § 302(b)(1) (2003) (codified in part at 42 U.S.C. § 1395w-3). This change followed successful pilot studies in two cities and began with a first round of competitive bidding in ten large metropolitan areas. Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4319 (authorizing pilot studies); 42 U.S.C. § 1395w-3(a)(1)(B)(i)(I) (requiring a limited area, first-round program in 2007). Congress then received feedback, issued further amendments, and provided by statute that the first round contracts were to be re-bid in a second round. Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275; see generally Texas Alliance for Home Care Servs. v. Sebelius, 681 F.3d 402, 405–06 (D.C. Cir. 2012) (discussing the genesis and evolution of the durable medical equipment competitive pricing program). Later, the second round took place and included many additional geographic bidding areas. The Minneapolis-St. Paul area is a second-round bidding area.

Because Key Medical primarily advances an *ultra vires* argument, it is important to note the plain text and overall structure of the amendments which show

the extent and nature of authority granted to the agency. Congress tasked the Agency with a broad and general mandate to "establish and implement programs under which competitive acquisition areas are established throughout the United States for . . . the furnishing under this part of competitively priced items and services." 42 U.S.C. § 1395w-3(a)(1)(A). In doing so, Congress granted relatively unconstrained authority to the Agency as to many issues, while narrowly defining and limiting authority as to other issues. This is evident in the statute's use of the terms "may" to identify factors for the Agency's discretionary consideration; "shall" to identify mandatory tasks; and "may not" or "shall not" to identify prohibited actions.

For example, 42 U.S.C. § 1395w-3 sub-parts (b)(4)(A) and (b)(4)(B), read together, show that the Secretary "may" limit the number of contractors awarded contracts for a bidding area, but "shall" grant contracts to multiple entities (i.e., the number of contractors may be reduced, but must be kept greater than one). Also, Congress gave the Agency discretion to choose products for inclusion in the competitive bidding system and expressly authorized—but did not require—the Agency to evaluate the relative medical efficacy of different items for inclusion, exclusion, or grouping purposes. See 42 U.S.C. § 1395w-3(b)(7) ("The Secretary *may* consider the clinical efficiency and value of specific items within codes, *including whether some items have a greater therapeutic advantage to individuals.*") (emphases added). Similarly, Congress granted the Agency the authority ("may establish") but not the obligation to specify certain items for exemption from competitive bidding and also to leave the use and "mode of delivery" of such items to physician discretion. See id. § 1395w-3(a)(5)(A). As these last two citations illustrate, Congress empowered the Agency to exercise its judgment and discretion in choosing the items that would be subjected to competitive bidding (and what items, due to perceived medical necessity, would not). Further, Congress prohibited payments to vendors who had not submitted bids for items and services and who had not been awarded contracts by the Agency. Id. § 1395w-3(b)(6)(A) ("payment shall not be made . . .").

Several sub-parts of the statute illustrate that Congress made timely implementation a priority. For example, Congress gave the Secretary discretion to waive more generally applicable acquisition regulations and provided that implementation was to move forward even if various quality-standard regulations were not complete. 42 U.S.C. § 1395w-3(a)(1)(C). Importantly for the present case, Congress also provided that seven broad types or categories of administrative actions in the process of creating and implementing these changes would be immune from judicial and administrative review:

- (b)(11) There shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, *or otherwise*, of—
  - (A) the establishment of payment amounts under paragraph (5);
  - (B) the awarding of contracts under this section;
  - (C) the designation of competitive acquisition areas under subsection (a)(1)(A) of this section and the identification of areas under subsection (a)(1)(D)(iii) of this section;
  - (D) the phased-in implementation . . . of this section...;
  - (E) the selection of items and services for competitive acquisition under subsection (a)(2) of this section;
  - (F) the bidding structure and number of contractors selected under this section; or
  - (G) the implementation of the special rule [concerning diabetic supplies].

42 U.S.C. § 1395w-3 (emphasis added). It is noteworthy that this ban on review is broad. Sub-part (b)(11) states that there "shall be no administrative or judicial review . . . *or otherwise*." And, the seven enumerated areas listed in the ban are categorical; the statute does not carve out reviewable and non-reviewable aspects of these seven categories. Sub-parts (b)(11)(A), (B), (E), and (F) are material to the present case—review is expressly barred as to "the establishment of payment amounts," "the

awarding of contracts," "the selection of items . . . for competitive acquisition," and "the bidding structure[.]"

B. Implementation of the Competitive Bidding System and Its Impact on Key Medical

Because the district court dismissed this case pursuant to Federal Rule of Civil Procedure 12(b)(1), we present the facts as asserted in Key Medical's complaint and in the light most favorable to Key Medical. See Great Rivers Habitat Alliance v. F.E.M.A., 615 F.3d 985, 988 (8th Cir. 2010). Enteral nutrition supplies, including low-profile, custom-fit feeding tubes are an important product for Key Medical's business.<sup>4</sup> Key Medical provided such feeding tubes to many customers, including some customers with developmental disabilities who were "dually eligible" for assistance from Medicare and also from Minnesota's Medicaid system. Key Medical explains that the interplay between these two medical payment programs requires that providers be eligible to receive payment from Medicare before they are allowed to

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<sup>4</sup>In its initial complaint, Key Medical provides a helpful description of regular and low-profile feeding tubes. Both types of tubes are for use with patients who have a stoma (an opening or portal) in their abdominal and stomach walls. The regular tubes are a much less expensive commodity that may extend for many inches outside the stoma. The low-profile tubes similarly enter through a stoma, but are custom fitted to end at skin level with a sealable port. Key Medical describes such ports as being roughly similar to the extendable inflation valves on beach balls. Key Medical argues low-profile tubes are medically superior if not necessary for some patients (e.g. infants, mentally diminished persons, persons subject to seizures or thrashing) because such patients cannot be stopped from pulling out normal tubes. Neither party discusses the means through which regular tubes might be secured to allow use with such special-needs patients, but it appears undisputed that regular tubes are not ideal for such patients. It also appears undisputed that special needs patients can, ultimately, receive nutrition with regular tubes, albeit with complications, additional labor, additional risks, inconvenience for the patients and caregivers, and added discomfort for the patients.

receive payment from Medicaid. For dually eligible patients, Medicaid is the payor of last resort and reimbursement requests must first be submitted to and denied by Medicare before Medicaid will reimburse providers.

Key Medical described differences and relationships between these two programs and explained how its own business coordinated with these programs prior to implementation of competitive bidding. First, Medicare would reimburse providers for low-profile tubes at a scheduled rate of approximately \$40 per tube and would allow replacement of a patient's tube once every 3 months. Medicaid, on the other hand would reimburse providers at a rate from \$140–\$530 per tube (depending on the particular tube) and allow replacements up to twice per month. For dually eligible patients, Key Medical would provide a first tube, billed to Medicare for approximately \$40 (at a substantial loss—Key Medical alleges the wholesale acquisition cost of such tubes ranges from \$100 to \$330). Key Medical would then sell additional tubes, Medicare would deny payment, and Medicaid, as the payor of last resort, would reimburse Key Medical at the higher and profitable price of \$140–\$530. Under this dual system, which Key Medical described as "far from perfect" and "convoluted," the Medicare-provided tubes were essentially loss leaders that Key Medical sold to be eligible to provide tubes later, at a profit, through the state Medicaid system.

Key Medical's primary grievance in this matter and the primary source of Key Medical's asserted financial harm stems from its *de facto* exclusion from Minnesota's Medicaid system. To understand this potential consequence of the Medicare competitive bidding system, we now turn to the competitive bidding system and its implementation process.

Key Medical explains that the Medicare competitive bidding process required entities to submit information demonstrating their financial health, explaining the quantity of product they could provide, and identifying a bid price at which the entity

could provide products. See 42 C.F.R. § 414.414(b). The Agency would then determine the quantity of product it anticipated would be needed in a geographic bidding area and set a single reimbursement price for all providers in that area. Id. (e)(1)–(2), (5). The single reimbursement price was based on the bid price at which the necessary quantity could be provided by the several providers whose bids were at or below that bid price. Id. (e)(5). Only providers who submitted bids were eligible to receive contracts, and providers could only receive a contract for a category of goods if they submitted bids for the items in that category. 42 U.S.C. § 1395w-3(b)(6)(A).

Key Medical's arguments in this case focus on the fact that the Agency did not allow providers free reign in constructing their own bids. Rather, in implementing the competitive bidding system, the Agency borrowed the pre-existing government-schedule prices as maximum bids that it would accept from bidders. In addition, the Agency required that parties' bids be sufficient to cover the providers' acquisition (wholesale) cost for the item plus some amounts for overhead and a reasonable profit. The parties refer to these requirements as the requirement that bids be "bona fide bids." The statute does not employ the term "bona fide bids." Agency regulations employ the term with reference to the requirements of applicable requests for bids. See 42 C.F.R. § 414.414(b)(4).

According to Key Medical, the pre-existing government-scheduled price for general feeding tubes is below Key Medical's acquisition cost for custom-fit, low-profile feeding tubes. Also according to Key Medical, the Agency established a website for vendors to use when submitting bids, but the site would not allow users to differentiate between types of feeding tubes or allow feedback to address such issues. Key Medical alleges this system prevented Key Medical from submitting a bona fide bid because Key Medical's acquisition cost for custom-fitted, low-profile tubes (more than \$100 per tube) exceeded by far the permissible bid cap for general

feeding tubes (approximately \$40), even without adding amounts for profit and overhead.

Key Medical also describes how the failure to submit a bona fide bid for an item or category carries severe consequences. Namely, the failure to submit a bid for a category of products (or the submission of a bid too low to cover the bidder's acquisition costs, some profits, and some overhead) results in that vendor's exclusion from receiving a contract for the entire associated category of products. Key Medical also asserts that, due to the interplay between the Medicare and Medicaid systems, Key Medical cannot serve as a Minnesota Medicaid provider unless it is eligible for payment from Medicare. In this regard, it appears uncontested that the Minnesota Medicaid system only allows payments to vendors who are also eligible for Medicare reimbursement because claims must be submitted first to Medicare and only secondarily to Medicaid (with Medicaid being the payor of last resort). According to Key Medical, this *de facto* exclusion from the Minnesota Medicaid regime for providing custom-fitted, low-profile feeding tubes causes Key Medical substantial profit loss and removes at least some choice of equipment provider from Key Medical's clients and former clients.

Implementation of the competitive bidding system resulted in a single competitive-bid price for feeding tubes in the Minneapolis-St. Paul area of less than \$40 and resulted in an award of contracts to 8 providers who listed local addresses and 14 mail-order or out-of-area providers to supply such tubes for Medicare (22 providers or vendors overall). Notwithstanding the awarding of contracts to 8 local bidders and 22 bidders overall, Key Medical argues that implementation has impermissibly reduced patient choice of provider. Key Medical also argues that many high-need patients may not have adequate access to low-profile feeding tubes.

### C. Procedural History

Key Medical brought the present action in the District of Minnesota, asserting a claim under the Administrative Procedures Act (APA) and also asserting constitutional violations. The APA claim alleged arbitrary and capricious agency action related to the use of the old price-schedule amounts as bid caps, the grouping together of regular and low-profile feeding tubes, and the bona fide bid requirement and its impact on vendors' ability to continuing participating in the separate Medicaid system. As relief, Key Medical sought to enjoin the Agency from: (1) implementing competitive bidding for "all Enteral Nutrients, Equipment, and Supplies," (2) utilizing a web-based bidding system "which rejects submissions of the actual and truthful acquisition costs," and (3) including in the competitive bidding program the provision of supplies to dually eligible patients.

The district court expressed substantial concern at the impact the Agency's competitive bidding regime would have upon dually eligible patients with developmental disabilities who use custom-fitted low-profile feeding tubes. The court, however, applied the bar on review and dismissed the APA claim for lack of jurisdiction. The court also held the constitutional claims were substantively insufficient to create jurisdiction under a constitutional-question exception to the statutory bar on review. Key Medical appeals.

## II. DISCUSSION

### A. General Applicability of the Bar on Review

We review a Rule 12(b)(1) dismissal *de novo*. Longaker v. Bos. Scientific Corp., 715 F.3d 658, 661 (8th Cir. 2013). In the absence of a viable *ultra vires* argument or constitutional claim, the § 1395w-3(b)(11) statutory bar applies to the

present facts.<sup>5</sup> The bar is clear on its face and broad in its listing of protected actions. See Texas Alliance for Home Care Servs., 681 F.3d at 409 ("The presumption of reviewability here is overcome by the specific and emphatic statutory language prohibiting judicial review of the competitive bidding procedure."); see also id. ("This language, combined with the broad range of subjects expressly immunized from review, manifest the Congress's intent to proceed with these initial administrative processes without risk of litigation blocking the execution of the program.") (internal quotation marks and citation omitted). As already noted, the several sub-parts of the bar define types of actions or decisions that are shielded from review, and the challenged actions fall within several of these categories: "(A) the establishment of payment amounts," "(B) the awarding of contracts," "(E) the selection of items and services for competitive acquisition," and "(F) the bidding structure and number of contractors selected[.]" 42 U.S.C. § 1395w-3(b)(11). Like the D.C. Circuit, we find no basis in the statute or otherwise to adopt a narrow construction of the facially broad and emphatic bar. See Amgen, Inc. v. Smith, 357 F.3d 103, 113 (D.C. Cir. 2004) ("If a no-review provision shields particular types of administrative action, a court may not inquire whether a challenged agency decision is arbitrary, capricious, or procedurally defective, but it must determine whether the challenged agency action is of the sort shielded from review.").

#### B. *Ultra Vires* Agency Action

Turning, then, to the possibility of review under an *ultra vires* theory, we reject Key Medical's characterization of the agency actions at issue as *ultra vires*. Although

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<sup>5</sup>The only opinion to construe the bar on review narrowly (and therefore in a manner potentially helpful to Key Medical) is a district court order from California that was subsequently vacated at the parties' request pursuant to a settlement agreement. See Sharp Healthcare v. Leavitt, 555 F. Supp. 2d 1121 (S.D. Cal. 2008), vacated by Order Granting Joint Motion to Vacate Court's Interlocutory Orders, Case No. 08–Civ.–170, Doc. Entry 53 (S.D. Cal. July 22, 2010).

an *ultra vires* action may be reviewed even in the face of statutory bar on review, our court has expressed a clear disinclination to accept plaintiffs' characterization of agency actions as *ultra vires* where it is possible to characterize a dispute merely as one of statutory interpretation concerning the scope of agency authority. See, e.g., Neb. State Legis. Bd., United Transp. Union v. Slater, 245 F.3d 656, 659–60 (8th Cir. 2001). Rather, in order for an agency action to be *ultra vires*, there must be a "plain violation of an unambiguous and mandatory provision of the statute." Id. at 659 (citation and internal quotation marks omitted). There is no such plain violation here.

In Nebraska State Legislative Board, our court rejected an *ultra vires* type argument in the face of a jurisdictional statute-of-limitations bar, stating:

As a general rule, courts "have interpreted [the *ultra vires* exception] as sanctioning [review] in a very narrow situation in which there is a 'plain' violation of an unambiguous and mandatory provision of the statute." American Airlines, Inc. v. Herman, 176 F.3d 283, 293 (5th Cir. 1999). Thus . . . "review of an 'agency action allegedly in excess of authority must not simply involve a dispute over statutory interpretation.'" Id. (quoting Kirby Corp. v. Pena, 109 F.3d 258, 269 (5th Cir. 1997)). Nor will a mere allegation of *ultra vires* action suffice. West v. Bergland, 611 F.2d 710, 717, 720 (8th Cir. 1979) ("Bergland"), cert. denied, 449 U.S. 821 (1980). In Bergland, although an appellant had characterized his challenge to a regulation as an *ultra vires* one, we disagreed, holding it was merely one of statutory construction. Id. at 717. Such is also the case here. FRA's decision to exempt certain employees from certification "is by no means a clear departure from [the] statutory mandate or an abridgment of [UTU's] statutory right." Id. at 718 (internal quotations omitted).

Id. at 659–60; see also Am. Soc'y of Cataract and Refractive Surgery v. Thompson, 279 F.3d 447, 456 (7th Cir. 2002) (rejecting an *ultra vires* argument in the context of a different Medicare provision and stating, "petitioners argue . . . the Secretary

violated a clear statutory mandate and exceeded the scope of her delegated authority [but] we . . . find the . . . regulation to be a reasonable interpretation of an unclear statutory mandate . . .") (internal citations omitted).

While Nebraska State Legislative Board involved a slightly different context than the present case, its discussion of what it means for an action to be *ultra vires* still applies. There, rather than a bar on judicial or administrative review, the issue was whether a request for review under the Hobbs Act could be entertained even though the request for review was filed after a 60-day jurisdictional limitations period had passed. 245 F.3d at 658. Even though the context was different, the impact was the same: a broad and general bar on jurisdiction cannot be avoided by characterizing mere fights over statutory interpretation as *ultra vires* claims.

In contrast, an example of a clearly *ultra vires* action and the violation of an unambiguous statutory mandate can be found in Leedom v. Kyne, 358 U.S. 184 (1958). There, the Supreme Court held that the National Labor Relations Board had taken an *ultra vires* action when, without the consent of professional workers, it approved a collective bargaining unit that included both professional and non-professional workers. 358 U.S. at 188–89. The action was deemed *ultra vires* because the authorizing statute, section 9(b)(1) of the National Labor Relations Act, expressly prohibited the inclusion of professional employees within such units without the consent of the professional employees. Id. Accordingly, the action in that case—agency action in direct contravention of an express and narrowly defined limit on agency authority—was deemed *ultra vires*. Id.

Some circuits have suggested a greater willingness to accept arguments characterizing agency action as *ultra vires* where the potentially applicable statutory bar is ambiguous or narrow. For example, the D.C. Circuit noted that review under a theory of *ultra vires* agency action "is favored . . . 'if the wording of a preclusion clause is less than absolute.'" Amgen, 357 F.3d at 112 (quoting Dart v. United States,

848 F.2d 217, 221 (D.C. Cir. 1988)). The court concluded, however, that the language at issue in Amgen—language almost identical to the bar on the present case— was clear and barred review. Id.

Although not articulated as a multi-factored test, these cases collectively illustrate the need to examine (1) the clarity and specificity of the bar on review; (2) the breadth of the Agency's statutory authorization; (3) the scope of any express statutory limits on the Agency's authority; and (4) the relationship between the action taken and these other three factors. In the present case, the bar on review is not only broad but lists in detail several aspects of the competitive bidding system using categorical language ("awarding of contracts," "selection of items," "the bidding structure") rather than targeting only small or specific aspects of the system. In addition, the statutory authority for the Agency's action is broad and relatively unconstrained: Congress made timely implementation a priority and gave the agency broad license to build a competitive-bidding system free of most judicial oversight. And, importantly, the actual detailed and specific actions that Key Medical complains about (the lumping together of regular and low-profile feedings tubes and the use of maximum bid caps), are within broad statutory authority and not contrary to any *specific* limits on authority.

Key Medical attempts to identify clear violations of statutory authority, but we conclude that, in each instance, Key Medical has identified mere issues of statutory interpretation. For example, 42 U.S.C. § 1395w-3(b)(2)(A)(iii) requires that competitive bidding for a category of products in a given bidding area only be adopted if overall cost savings are realized for the category. Key Medical argues that adoption of the pre-existing, government-defined scheduled price as the maximum bid cap effectively imposes a requirement of item-by-item cost savings rather than category-based cost savings. While this may be true, it does not make the Agency's action *ultra vires*. This argument presents only a question of statutory interpretation because Congress did not instruct the Agency as to how to ensure or achieve

category-wide cost savings. And, the use of pre-existing scheduled prices as maximum bid caps is not "a clear departure from [the] statutory mandate," Bergland, 611 F.2d at 718 (internal quotation marks omitted), of ensuring category-wide cost savings.

Still focusing on the maximum bid cap, Key Medical argues that such caps are inherently non-competitive, are not bid-based, and, as such, are in conflict with a statutory mandate to establish a system of competitive pricing under which payments "shall be based on bids submitted and accepted . . . ." 42 U.S.C. § 1395w-3(b)(5)(A). Again, we conclude this argument presents a mere question of statutory interpretation rather than a clear and unambiguous statutory violation. Congress did not instruct the Agency as to how to design a competitive bidding system, and Congress did not expressly preclude the use of non-competitively derived elements within such a system. Simply put, Congress instructed to the Agency to design a system under which payments would be "based on bids submitted and accepted," but Congress did not exclude the consideration or reliance on other, additional factors when establishing payment amounts.

Also, it is a matter of statutory interpretation whether the term "bid" must be viewed as inherently limited to unconstrained bids by market participants or whether the Agency may impose limitations on permissible bids. Congress defined the term bid to mean "an offer to furnish an item or services for a particular price and time period that includes, where appropriate, any services that are attendant to the furnishing of the item or service." 42 U.S.C. § 1395w-3(b)(6)(B). This definition does not necessarily preclude the Agency from imposing a price ceiling or from imposing requirements as reflected in the Agency's requirement for "bona fide bids." Because this issue, like all *ultra vires* arguments Key Medical raises in this case, presents a matter of statutory interpretation rather than a clear statutory violation, we must reject Key Medical's attempt to avoid the bar on review under an *ultra vires*

theory. Neb. St. Legis. Bd., 245 F.3d at 659 (finding no "'plain' violation of an unambiguous and mandatory provision of the statute") (citation omitted).<sup>6</sup>

Finally, Key Medical argues that implementation of the competitive bidding regime impermissibly infringes on patients' protected choice of provider. This argument is without merit as the statute implicitly anticipates a reduction in patient choice by expressly granting the Agency authority to "limit the number of contractors in a competitive acquisition area, 42 U.S.C. § 1395w-3(b)(4)(A), while requiring only that the Agency "award contracts to multiple entities," id. (b)(4)(B).

### C. Constitutional-Claim Exception

Regarding the constitutional claims, Key Medical argues that implementation of the competitive bidding regime amounted to an unconstitutional taking of its business. Key Medical also argues it was deprived of a valuable property interest in its business without due process.<sup>7</sup> Key Medical advances these arguments in an effort to obtain review under a constitutional-claim exception to the statutory bar on review. See, e.g., McNary v. Haitian Refugee Ctr., Inc., 498 U.S. 479, 495 (1991)

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<sup>6</sup>Key Medical's arguments concerning the interplay of the competitive bidding system with the separate Minnesota Medicaid system are similarly without merit. In this regard, Key Medical identifies a consequence of the competitive bidding system rather than a clearly *ultra vires* aspect of the system or its implementation. Congress did not mandate that the Agency avoid or even consider the impact upon state Medicaid systems in design and implementation of the competitive bidding system. We therefore make no comment as to the merit of Key Medical's claims of unfairness and unintended consequences. We note merely that our inquiry is limited to whether the Agency acted in such derogation of its authority as to act in an *ultra vires* matter that might permit our Court to exercise jurisdiction notwithstanding the bar on review.

<sup>7</sup>Key Medical does not fully articulate distinct arguments, instead blending the concepts of due process rights and protections against takings into one.

(distinguishing between the application of a statutory bar to simple claims for relief from administrative decisions versus substantial collateral constitutional challenges that might not otherwise be subject to review); see also Hernandez v. Holder, 438 F. App'x 527, \*1 (8th Cir. 2011) (complying with the Immigration and Naturalization Act's bar on review of certain final orders of removal, but noting that the petitioner had not raised "any substantial constitutional challenge"). Where an asserted basis of federal jurisdiction is "patently meritless" however, a plaintiff cannot avoid application of a bar on review. See Biscann v. Merrill Lynch & Co., 407 F.3d 905, 907 (8th Cir. 2005).

Here, Key Medical possesses no protected interest that can serve as the basis for a takings claim, nor a property interest that may serve as the basis of a due process violation. In Minnesota Association of Health Care Facilities, Inc. v. Minnesota Department of Public Welfare, 742 F.2d 442, 446 (8th Cir. 1984), the Eighth Circuit rejected a plaintiff's attempt to characterize a loss of business associated with a condition on Medicaid participation as a taking. There, the court stated, "[d]espite the strong financial inducement to participate in Medicaid," the care provider's choice to participate in Medicaid was "nonetheless voluntary." Id. Our court concluded, "[t]his voluntariness forecloses the possibility that the statute could result in an imposed taking of private property which would give rise to the constitutional right of just compensation[.]" Id.; see also Am. Soc'y of Cataract & Refractive Surg., 279 F.3d at 455–56 (physicians had no property interest in particular method for establishing new reimbursement payment regime and as such no "substantial constitutional issues" existed that could overcome a Medicare statutory bar on review). Minnesota Association of Health Care Facilities controls in the present case. Because the constitutional claim lacks merit due to the absence of a protected property or liberty interest, it is not "a *substantial* constitutional challenge" capable of overcoming the bar on review. Am. Soc'y of Cataract & Refractive Surg., 279 F.3d at 456 (emphasis added).

We affirm the judgment of the district court.

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